MEDICAL PRACTICE

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Flowering of American bioethics

BARBARA J CULLITON, WALLACE K WATERFALL

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Washington, DC—The recent birth of Louise Joy Brown is being considered at the highest levels of the federal government here by officials, who have to decide whether a baby conceived in vitro should ever be allowed to be born in the USA. Health, Education, and Welfare Secretary Joseph A Califano, jun, has gone so far as to call for a thorough national debate on the subject. From the moment Steptoe and Edwards told the *Daily Mail* that the birth was imminent, leaders of the biomedical establishment here have been asking not whether the baby would be a boy or a girl but whether its presumably unprecedented manner of coming into being is ethical. Califano has charged his newly formed Ethics Advisory Board with producing an answer.

This political reaction to the birth of a baby is perhaps the ultimate confirmation of the flowering of bioethics in America. A decade ago there was only a handful of bioethicists in the country—small numbers of theologians, philosophers, sociologists, and others—who concerned themselves with ethical questions about biomedical research. Today, much more numerous, they are recognised as scholars of a distinct intellectual discipline, and the presence of a bioethicist is required by regulation on any number of academic and national policy-making committees. The principle task of the bioethicist on these committees is to act as society's conscience in matters once left entirely to the medical and research professions. It is the bioethicist who sensitises clinical investigators to patients' rights and raises complex issues that once were omitted from the research plan. To wit: what is the "moral" or "human" status of the embryo that became Louise Brown? What about the other human embryos that were created in vitro and discarded?

5026 Eskridge Terrace NW, Washington, DC 20016, USA

BARBARA J CULLITON, AB, is News Editor of *Science*, the weekly journal of the American Association for the Advancement of Science

WALLACE K WATERFALL, AB, is Senior Professional Associate and Director, Office of Communications, Institute of Medicine, National Academy of Sciences

Beginnings of federal nurture

The federal nurturing of bioethics in the United States began in the late 1960s, when the drama of human heart transplantation captured the public imagination. People wondered whether it was "right" to transplant an organ thought to be so directly linked to our emotions. People were concerned about the problem of choosing recipients for donor hearts, which are always scarce. Renal dialysis posed similar questions. How should we decide "Who shall live and who shall die?" In that atmosphere of uncertainty, then Senator Walter F Mondale (now Vice-President) suggested the creation of a national body of some sort that would deal with these and other delicate issues that might arise from the inexorable march of technology. But there was little response in the Senate or from the public. The research community shuddered, and then dismissed Mondale's idea as foolish meddling. For a time it lay dormant.

Then, in the early 1970s, a few cases of rank ethical insensitivity, some known earlier to the scientific community, were revealed before the Congress in a series of headline-making hearings. There was the case of the physician who gave cancer cells to dying patients to see if they'd get cancer. There was the sterilisation of two retarded girls without proper consent. The "experiment" of old black men with syphilis going untreated even after penicillin had been discovered (they were a control group) caused a great furore. And, in the wake of the Supreme Court's controversial 1973 decision legalising abortion, the issue of fetal research became prominent. True to form, Congress reacted. All in one legislative breath in 1974 it passed a bill that (*a*) imposed a moratorium on fetal research and (*b*) established a panel of scientists and bioethicists to decide whether the moratorium should be lifted. Thus the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, for which there is no satisfactory

acronym, came into being. Mandated to look at a number of issues in addition to fetal research—research on children, prisoners, the mentally infirm, and psychosurgery—this unique body was instructed to meet in public and the Secretary of HEW, to whom it reported, was required by law to publish, unedited, each of the commission's recommendations. If he chose not to follow them exactly, he had to explain his reasons in writing and publish them for public comment. Although the commission was an advisory body only, these provisions gave it unusual authority.

Commissioners and their work

Commission members, chosen by a thoroughly political process, represented a diverse set of constituents—researchers, civil rights lawyers, antiabortionists, racial minorities, and, of course, bioethicists of various persuasions. The commissioners, skilfully chaired by Harvard obstetrician Kenneth J Ryan, came to their task with a variety of biases, but worked hard, meeting monthly for nearly four years, to accommodate one another's views. Always there was a struggle to balance what was ethically sound with respect to the individual with that which was scientifically valuable to the community. Almost always there was a reasoned compromise. The commission lifted the ban on fetal research, for instance, but carefully stipulated the circumstances under which it was to be allowed. In each of the issues it considered, obtaining the informed consent of the participants in research figured prominently in the ethical prescription the commission wrote. Today, at every research institution in the country that receives federal funds (which takes in most of them) local institutional review boards study each new protocol for its compliance with ethical principles.

By law, the Ryan Commission was a temporary body: it held its last meeting in September. And again, by law, there is a political inevitability: a new commission to take the old one's place, this time a permanent body called the Ethics Advisory Board, advisory to the Secretary of Health, Education, and Welfare. It is this successor group, which first met only last May, that must decide the ethical meaning of Louise Brown's conception. As infertile couples looked longingly across the Atlantic for a novel solution to their inability to have a child, the board met in a conference room at the National Institutes of Health, where it received the Secretary's instructions to begin deliberations immediately on whether to allow research on in-vitro fertilisation and embryo transfer in the United States, where there has been a moratorium on such work for several years.

Although the subject of in-vitro fertilisation had been on the Ethics Advisory Board's agenda from the start, it was Louise Brown that moved it to the top of the list. Secretary Califano's memo outlined his opinion: "In May, I referred to the Ethics Advisory Board an application that sought funds from the National Institutes of Health to perform research involving human in-vitro fertilisation. At that time the practical application of the research seemed years away. We have now seen the work of Professor Edwards and Mr Steptoe. . . . This achievement has aroused great interest throughout the world. Research on in-vitro fertilisation and embryo transplantation holds enormous promise. At the same time, it raises questions that reach to our most profound moral and ethical beliefs."

Scientific and ethical testimony

For two days the board, chaired by James C Gaither, a San Francisco attorney who is a friend of Secretary Califano, met under the glare of television lights while it heard testimony on the scientific and ethical "facts" of the matter and also heard many difficult questions raised. Is in-vitro fertilisation morally acceptable? Does it fundamentally alter our view of the family? What are the chances a baby conceived in vitro will be abnormal, Califano asked, through his memo, "Will this research lead to selective breeding, to attempts to control the genetic make-up of offspring or to the use of 'surrogate parents,' where, for example, rich women might pay poor women to carry their children." What about infertile couples adopting an embryo? And, in hard, legal practicality, there was also this question from the Secretary: "Are any of the participants—such as the research investigator, the clinical practitioner, the hospital or university, the government funding agency—legally liable for defects of a child conceived in the course of such research?"

In keeping with the current American trend to conduct scientific and ethical debates with the fullest public participation, Califano further instructed the board (much to its surprise) that, "In the course of your consultations, you should arrange for public hearings throughout the nation . . . to stimulate a national debate on this subject, and to assure that all interested parties have an opportunity to make their views known."

Speaking from the standpoint of formal biomedical ethics, LeRoy Walters, director of the Centre for Bioethics at the Kennedy Institute of Ethics, Georgetown University, presented to the board a survey of the "ethical" literature and, when pressed for his own opinion, said he thought that the "moral status" of a human embryo conceived in vitro was "more than a mouse embryo but less than that of a full human fetus." Walters thinks that research on a preimplantation human embryo up to about 14 days in vitro ought to be permitted on grounds that the benefits to society from the research could be great. On the other side, Paul Ramsey, a conservative bioethicist/theologian from Princeton University, declared in written testimony to the Board that "in vitro fertilisation and embryo transfer should not be allowed by medical policy or public policy in the United States—not now, nor ever."

Research into early development

While it is weighing these difficult questions, the board also is supposed to reach a judgment on the ethical quality of an application by Pierre Soupart of Vanderbilt University, whose proposal to do research on in-vitro fertilisation is pending before the National Institutes of Health. Soupart wants to take ova during routine gynaecological surgery, fertilise them in vitro with donor sperm, and observe the development of the resulting embryos for no more than six days in culture. His objective is to look for chromosomal and morphological characteristics in the hope of learning something about the early detection of abnormal embryos. No embryo transfer to a woman is anticipated under the present grant application, which has been approved for funding by the NIH and awaits only the approval of the board. The grant has been pending since 1975, and is the only one of its kind up for ethical review.

Chairman Gaither says he hopes that the board will be able to work quickly, particularly with respect to Soupart's application, but, in the light of Califano's call for a full national debate, there is little doubt that the board's deliberations will be protracted.

It is difficult to know what the United States' current commitment to bioethics will mean for the future conduct of research. There seems to be a consensus that concern with ethical issues is appropriate but there are few data to indicate how beneficial it has been thus far and it is recognised that blatant abuse is always possible. On the other hand, there is some small concern that in our attraction to bioethics we may be overdoing it. Is it possible, for instance, that stringent protection of the rights of individual children and pregnant women may be precluding research needed to answer questions about drug metabolism during childhood and pregnancy? The sound policy making of the Ryan Commission reflected a careful balancing of the risks of research to the individual versus the benefits to society. But there may come a time when we have to weigh the benefits to society against the risks of too stringent an ethical view.